Notice of Allowability	Application No.	Applicant(s)	
	08/070,099	NEWMAN ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *amendment after final filed 1/10/2005*.

2. ☒ The allowed claim(s) is/are *1-9*.

3. ☐ The drawings filed on _____ are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☒ to Paper No./Mail Date *4/4/1994*.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *5/5/2005* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER
05/10/2005

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Brian Poor on May 5, 2005.

The application has been amended as follows:

In the claims:

Claim 10 has been canceled.

Claim 1. A monoclonal antibody that [is capable of] specifically [binding] binds to intrinsic factor only in the absence of vitamin B12 and exhibits an increase in the first order dissociation rate of the antibody-intrinsic factor complex in the presence of vitamin B12, wherein the dissociation rate is dependent on the concentration of vitamin B12.

Claim 5. A kit for assaying for vitamin B12 in a sample comprising (a) a solid phase support to which is bound a predetermined amount of [an] a monoclonal antibody that is capable of specifically binding to intrinsic factor only in the absence of vitamin B12 and exhibits an increase in the first order dissociation rate of the antibody-intrinsic factor complex in the

presence of vitamin B12, wherein the dissociation rate is dependent on the concentration of vitamin B12, and (b) a predetermined amount of a labelled intrinsic factor.

Claim 7. A method of obtaining a monoclonal antibody [capable of binding] that binds to intrinsic factor only in the absence of vitamin B12, and exhibiting an increase in the first order dissociation rate of the antibody-intrinsic factor complex in the presence of vitamin Bl2, wherein the dissociation rate is dependent on the concentration of vitamin B12, comprising the steps of:

a) immunizing an animal with substantially purified intrinsic factor;

b) isolating splenic lymphocytes from the immunized animal;

c) fusing the isolated splenic lymphocytes with a plasmocytoma cell line to obtain a plurality of hybridoma clones which secrete antibody;

d) extracting free vitamin B12 from a predetermined amount of culture supernatant containing antibody from each hybridoma clone;

e) contacting a first sample of each extracted antibody-containing supernatant with intrinsic factor in the presence of vitamin B12;

f) contacting a second sample of each extracted antibody-containing supernatant with intrinsic factor in the absence of vitamin B12;

g) contacting an enzyme labelled antibody which specifically binds to immunoglobulin with each of the first and second samples;

h) detecting the presence of labelled antibody present in each of the first and second samples; and

i) isolating the hybridomas which secrete antibodies which [bound] bind to intrinsic factor only in the absence of vitamin B12 and exhibit an increase in the first order dissociation rate of the antibody-intrinsic factor complex in the presence of vitamin B12, wherein the dissociation rate is dependent on the concentration of vitamin B12.

Claim 9. A diagnostic assay method for determining the amount of vitamin B12 in a liquid sample comprising:

(a) contacting the sample with a known amount of labeled intrinsic factor and a known amount of [an] a monoclonal antibody bound to a solid phase, wherein the antibody specifically binds to intrinsic factor [said antibody being capable of binding to] at a site on intrinsic factor that is distinct from the site on intrinsic factor to which vitamin B12 binds and which binds to intrinsic factor only in the absence of vitamin B12, and that exhibits an increase in the first order dissociation rate of the antibody-intrinsic factor complex in the presence of

vitamin B12, said dissociation rate being dependent on the concentration of vitamin B12, wherein the intrinsic factor will specifically bind to vitamin B12 in the sample to form a vitamin B12-intrinsic factor complex;

(b) separating the vitamin B12-intrinsic factor complex from the monoclonal antibody bound to the solid phase; and

(c) determining the amount of vitamin B12 by measuring the amount of label associated with the vitamin B12-intrinsic factor complex or the amount of label bound to the antibody on the solid phase.

Please note that the dependency of claim 8 has been corrected, according to the correction (Rule 1.126) made to the original claims in the Office action mailed 4/4/1994. Claim 8 is dependent from claim 7.

Claim 8. (Amended) The method of claim [8] 7, wherein the extraction step (d) is performed using dextran coated charcoal.

In the specification:

On page 1, line 15, before "Field of Invention", the following was added:

--This application is a continuation-in-part of U.S. Application No. 07/682,060, filed April 9, 1991, now abandoned.--

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
May 6, 2005